Division of Medical Assistance	Clinical Coverage Policy No. 11C
Ventricular Assist Devices	Original Date: January 1, 1994
	Revised Date: December 1, 2005

1.0 Definition of the Procedure

Ventricular assist devices provide temporary mechanical circulatory support for patients awaiting a heart transplant, which are not expected to survive until a heart is available. Three such devices are available and have been used in patients, who are transplant candidates, but whose hemodynamics are inadequate, even with the use of intravenous inotropic agents. The heart mate ventricular assist pump is a pneumatically powered device that is implanted in the left upper quadrant of the abdomen. The thoratec assist pump is a pneumatically powered device that is placed on the anterior abdominal wall. The novacor ventricular assist pump is an electrically powered device implanted in the left upper quadrant, and the electric line and vent tube are passed through the lower abdominal wall.

2.0 Eligible Recipients

2.1 General Provisions

Medicaid eligible individuals with a need for this specialized treatment confirmed by a licensed physician are eligible as long as they meet individual eligibility requirements. Medicaid recipients may have service restrictions due to their eligibility category, which would make them ineligible for this service.

2.2 Special Provisions

Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) is a federal Medicaid requirement that provides recipients under the age of 21 with medically necessary health care to correct or ameliorate a defect, physical or mental illness or a condition identified through a screening examination. While there is no requirement that the service, product or procedure be included in the State Medicaid Plan, it must be listed in the federal law at 42 U.S.C. § 1396d(a). Service limitations on scope, amount or frequency described in this coverage policy do not apply if the product, service or procedure is medically necessary.

The Division of Medical Assistance's policy instructions pertaining to EPSDT are available online at http://www.dhhs.state.nc.us/dma/prov.htm.

3.0 When the Procedure is Covered

Each recipient's condition is evaluated on an individual basis. There may be other conditions that are indications for coverage.

The N.C. Medicaid program covers ventricular assist devices for patients of all ages who meet the following criteria:

1. as a bridge to heart transplantation for patients who are listed as heart transplant candidates
2. for short-term use for patients post cardiotomy who are unable to be weaned off cardiopulmonary bypass
3. as destination therapy for patients who meet all the following criteria:
   a. documented ineligibility for heart transplantation
   b. end stage heart failure

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c. peak oxygen consumption less than or equal to 14ml/kg per minute, and
- NYHA class IV* heart failure for at least 60 days, or
- NYHA class III/IV* for at least 28 days and on intraaortic balloon pump for at least 14 of those days, or
- dependent on IV inotropic medications, with two weaning attempts.

***Note:** NYHA Class III - marked limitation of activity, less than ordinary activity leads to symptoms.

NYHA Class IV - inability to carry on any activity without symptoms. Symptoms may be present at total rest.

4.0 When the Procedure is Not Covered

Ventricular assist devices are not covered when the medical necessity criteria listed in **Section 3.0** are not met. Each recipient's condition is evaluated on an individual basis. There may be other conditions that are indications for non-coverage.

4.1 History of or Active Substance Abuse

Must have documentation of substance abuse program completion plus six months of negative sequential random drug screens.

Note: To satisfy the requirement for sequential testing as designated in this policy, the Division of Medical Assistance (DMA) must receive a series of test (alcohol and drug) results spanning a minimum six-month period, allowing no fewer than a three-week interval and no more than six-week interval between each test during the given time period. A complete clinical packet for prior approval must include at least one documented test performed within one month of the date of request to be considered.

4.2 Psychosocial History

Psychosocial history that would limit ability to comply with medical care pre and post transplant.

4.3 Medical Compliance

Current patient and/or caretaker non-compliance that would make compliance with a disciplined medical regime improbable.

5.0 Requirements for and Limitations on Coverage

All applicable N.C. Medicaid policies and procedures must be followed in addition to the ones listed in this procedure.

All procedures must be prior approved by DMA.

6.0 Providers Eligible to Bill for the Procedure

Physicians enrolled in the N.C. Medicaid program who perform this procedure may bill for this service.

7.0 Additional Requirements

FDA approved procedures, products, and devices for implantation must be utilized.

Implants, products, and devices must be used in accordance with all FDA requirements current at the time of surgery.

A statement signed by the surgeon certifying all FDA requirements for the implants, products, and devices must be retained in the recipient's medical record and made available for review upon request.

8.0 Policy Implementation/Revision Information

Original Effective Date: January 1, 1994

Revision Information:

Date	Section Revised	Change
7/1/05	Entire Policy	Policy was updated to include coverage criteria effective with approved date of State Plan amendment 4/1/05.
9/1/05	Section 2.2	The special provision related to EPSDT was revised.
12/1/05	Section 2.2	The web address for DMA's EDPST policy instructions was added to this section.

Attachment A
Claims Related Information

Reimbursement requires compliance with all Medicaid guidelines including obtaining appropriate referrals for recipients enrolled in the Medicaid Managed Care programs.

A. Claim Type

1. Physicians bill professional services on the CMS-1500 claim form.
2. Hospitals bill for services on the UB-92 claim form.

B. Diagnosis Codes

Providers must bill the ICD-9-CM diagnosis code to the highest level of specificity that supports medical necessity.

C. Procedure Codes

Codes that are covered include:

33975	33976	33977	33978	33979	33980

D. Providers must bill their usual and customary charges.